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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,052	06/02/2005	Allan Shepard	2335 US F	8397

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,052	SHEPARD ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-8* is/are pending in the application.

4a) Of the above claim(s) *3-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed February 26, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 1 and 4 have been amended.

   b. Claim 2 has been cancelled.

2. For clarification, the previous office action states that Claims 1-2 were present for examination and claims 3-8 were withdrawn as being directed to the non-elected inventions and species election. Claims 5-8 were withdrawn due to election of Group I and claims 3-4 were withdrawn as these claims were not readable on the elected species of SB 331750 or the species tunicamycin which was included due to the examiner's expansion of the cathepsin K antagonist.

3. Claims 1, 3-8 are pending in the case.

4. Claim 1 is present for examination.

5. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

6. All grounds not addressed in the action are withdrawn or moot.

7. New grounds of rejection are set forth in the current office action.

Claim Objections

8. Claim 1 is objected to because of the following informalities: 5-(2-morpholin-4-yl-thoxy)-benzofuran-2-carboxylic acid ((S)-3-methyl-1-[3-oxo-1-[2-(3-pyridin-2-yl-phenyl)-

ethenoyl]-azepan-4-ylcarbanoyl)-butyl)-amide is misspelled and has non-corresponding brackets. Appropriate correction is required.

New Grounds of Rejection

9. Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "pyridoxal propionate derivatives" is indefinite as it unclear is encompassed by the term and given the form any number of compounds given an infinite number of chemical reactions, the compounds and be anything and thereby it is unclear what is envisioned for the invention. It does not allow one of skill in the art to know the metes and bounds of the invention.

12. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is unclear as it recites cyanamides twice. It is unclear if it is the same term and mistakenly placed twice or if the second recitation of the term is meant to refer to something else. It does not allow one of skill in the art to know the metes and bounds of the invention.

Claim Rejections - 35 USC § 102/103

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Banerjee et al. teaches a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions include neovascular glaucoma (Abstract, paragraph 29, 38, 41, 85, 99, 103-104, 110, 193-199, 207, 212, Claim 1, 5, 9, 15, and 18). Inhibition of angiogenesis in neovascular glaucoma inherently reduces intraocular pressure as it is known in the art that neovascular glaucoma is a result of the angiogenesis factors where new capillary growth, leakage, and scaring results in intraocular pressure. Inhibition of angiogenesis inherently inhibits the cascade and lowers the intraocular pressure.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Alternatively, for completeness of prosecution, purely arguendo for this claim, insofar that the recitation of lowering intraocular pressure is not specifically recited, claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Banerjee et al. teaches a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions include neovascular glaucoma (Abstract, paragraph 29, 38, 41, 85, 99, 103-104, 110, 193-199, 207, 212, Claim 1, 5, 9, 15, and 18). It would be obvious to one of skill in the art to utilize the method for inhibiting angiogenesis as taught by Banerjee et al. comprising administering a composition comprising a nucleoside, particularly tunicamycin for conditions such as neovascular glaucoma for lowering intraocular pressure as it is known in the art that neovascular glaucoma characterized by increased intraocular pressure resulting from angiogenesis factors where new capillary growth, leakage, and scaring results in intraocular pressure (evidenced by Gurwood et al., Discussion; Hunter et al., U.S. Pat. 5886026 line 47-Col. 34 line 18, U.S. Pat. Pub. 2002/0192280 paragraph 139-140). It would have been obvious to utilize a method that treats and inhibits the angiogenic source of neovascular glaucoma, to treat, inhibit, and reduce the resulting consequences of neovascular glaucoma such as intraocular pressure.

One of ordinary skill in the art would have been motivated to do this because it is desirable to use a product to treat not only the condition but also its resulting consequences.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Banerjee et al. teaches a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions include neovascular glaucoma (Abstract, paragraph 29, 38, 41, 85, 99, 103-104, 110, 193-199, 207, 212, Claim 1, 5, 9, 15, and 18). Inhibition of angiogenesis in neovascular glaucoma inherently reduces intraocular pressure as it is known in the art that neovascular glaucoma is a result of the angiogenesis factors where new capillary growth, leakage, and scaring results in intraocular pressure. Inhibition of angiogenesis inherently inhibits the cascade and lowers the intraocular pressure.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Alternatively, for completeness of prosecution, purely arguendo for this claim, insofar that the recitation of lowering intraocular pressure is not specifically recited, claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Banerjee et al. teaches a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions include neovascular glaucoma (Abstract, paragraph 29, 38, 41, 85, 99, 103-104, 110, 193-199, 207, 212, Claim 1, 5, 9, 15, and 18). It would be obvious to one of skill in the art to utilize the method for inhibiting angiogenesis as taught by Banerjee et al. comprising administering a composition comprising a nucleoside, particularly tunicamycin for conditions such as neovascular glaucoma for lowering intraocular pressure as it is known in the art that neovascular glaucoma characterized by increased intraocular pressure resulting from angiogenesis factors where new capillary growth, leakage, and scaring results in intraocular pressure (evidenced by Gurwood et al., Discussion; Hunter et al., U.S. Pat. 5886026 line 47-Col. 34 line 18, U.S. Pat. Pub. 2002/0192280 paragraph 139-140). It would have been obvious to utilize a method that treats and inhibits the angiogenic source of neovascular glaucoma, to treat, inhibit, and reduce the resulting consequences of neovascular glaucoma such as intraocular pressure.

One of ordinary skill in the art would have been motivated to do this because it is desirable to use a product to treat not only the condition but also its resulting consequences.

Response to Arguments

17. Applicant's arguments in regards to the term "derivative" filed 2/26/2009 have been fully considered and as cited by Applicant, are moot in light of the amendments, but is still applicable to the term "pyridoxal propionate derivatives" as addressed above.

18. Claim 1-2 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Claim 2 is cancelled, the rejection is moot.

Applicant's arguments filed 2/26/2009 have been fully considered but they are not persuasive. Applicant asserts that the Banerjee et al. does not teach a method of lowering intraocular pressure with the administration of a cathepsin K antagonist and that elevated intraocular pressure associated with glaucoma is not associated with angiogenesis and that neovascular glaucoma is not typically associated with elevated intraocular pressure. This is not persuasive as is it known in the art that neovascular glaucoma presents with intraocular pressure and that the intraocular pressure in neovascular glaucoma is a result of angiogenesis as evidenced by Hunter et al. (U.S. Pat. 5886026 line 47-Col. 34 line 18, U.S. Pat. Pub. 2002/0192280 paragraph 139-140) and Gurwood et al. (Discussion). The inhibition of the angiogenesis would inherently inhibit the cascade in neovascular glaucoma affecting the intraocular pressure which has been known and pursued in the art for many years. It is also known in the art that

most angiogenic inhibitors have intraocular pressure reducing properties (e.g. Clark-U.S. Pat.6172054, Col. 1 line 50-66).

Accordingly, the rejection is maintained.

Conclusion

19. Claim 1 is rejected.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612